REMARKS

Claims 1-27 are pending in the application. Claims 8-18 and 20-25 are withdrawn.

The Office Action states that "the provisional applications upon which priority is claimed fails to fully provide adequate support under 35 U.S.C. § 112 for claims 1-7, 19 and 26-27" (Office Action, page 2, first paragraph). Applicants respectfully disagree.

The presently claimed invention is directed to "[a] vaccine for Newcastle disease comprising a Newcastle disease virus Z, wherein the Newcastle disease virus Z has at least two of the features selected from the group consisting of (1) a F_0 protein cleavage site having at least two less basic amino acid residues than a F_0 protein cleavage site of Newcastle disease virus wild type strain Beaudette C; (2) an amino acid having a non-aromatic side chain at the N terminus of the F_1 cleavage fragment, wherein the amino acid having a non-aromatic side chain is glycine, alanine, valine, leucine or isoleucine; and (3) an open reading frame of a HN glycoprotein being longer than an open reading frame of a HN glycoprotein of Newcastle disease virus wild type strain Beaudette C" (claim 1).

Applicants respectfully submit that the subject matter of claims 1-7, 19 and 26-27 is supported by the provisional applications upon which priority is claimed. For example, U.S. Patent Provisional Application No. 60/171,072 ("the '072 provisional") states the following:

> ... Sequence analysis of several avirulent strains [of Newcastle disease virus (NDV)] have suggested that attenuation in NDV occurs by three different mechanisms: (1) avirulent strains have few basic residues (x-Arg/lys-x-x-Arg) at the F0 protein cleavage site, where as virulent strains have multibasic residues (Arg-Arg-x-

> Arg/lys-Arg) at the F0 protein cleavage site, (2) in some avirulent strains the open reading frame of the HN glycoprotein extends beyond the C terminus of more virulent strains and this terminal extension was assumed to be responsible for the origin of the HN precursor (HN0) found in avirulent strains, and (3) in some avirulent strains a leucine residue is present at the N terminus of the F1 cleavage fragment in place of a phenylalamine reside at this position in virulent strains ('072 provisional, page 1, lines 9-17).
>
> ... We propose to engineer attenuated NDV vaccine strains by combining all three mechanisms of attenuation ('072 provisional, page 2, first paragraph).
>
> ... We propose to recover NDV with amino acid changes at the cleavage site. The codon of the changed amino acid changes at the cleavage site. The codon of the changed amino acid will be different from that of the original amino acid by at least two nucleotides; therefore, will stabilize reversion to a basic residue ('072 provisional, page 2, second paragraph).
>
> ... The above changes will not only be done in our existing full-length cDNA clone of NDV Strain Beaudette C ... ('072 provisional, page 2, lines 9-10).
>
> ... In our proposed recombinant NDV strains the codes of the amino acids in the cleavage site will be changed so that they will contain the same amino acids as other avirulent strains but will require reversion of five or six nucleotides. ... Furthermore, our NDV vaccines will also contain the other two mechanisms of attenuation, presence of Leucine in +1 position and cleavable HN protein. ('072 provisional, paragraph bridging pages 5-6).

Meanwhile, U.S. Provisional Patent Application No. 60/132,597 ("the '597 provisional") discloses a complete map of the genome of Newcastle disease virus (NDV) strain Beaudette C depicted by Figure 3 and described on page 7 ("the genome of NDV strain Beaudette C is 15,186 nucleotides").

In particular, claims 26-27 are supported by page 5, last line of the '072 provisional ("[a] genetically engineered NDV carrying cytokine genes") and page 2, last sentence and page 8, lines 21-22 (and page 8, last line) of the '597 provisional ("the

genes for cytokines can be inserted into the NDV genome for coexpression"). Thus, Applicants submit that the provisional applications provide adequate written support for claims 26-27.

Claims 1-7, 19 and 26-27 are rejected under 35 U.S.C. § 112, first paragraph, for insufficient written description. This rejection is traversed.

Applicants respectfully submit that the specification provides adequate written support for claims 1-7, 19 and 26-27. As noted by the Examiner, "[i]t is well settled that the claimed subject matter need not be supported by an explicit, word for word recitation, but something more than a suggestion is needed to satisfy the requirement for an adequate written description" (Office Action, page 4, lines 14-16). However, Applicants submit that "an explicit, word for word recitation" is present, as the claims are original and are adequately supported by the specification.

Under MPEP § 2163.03 a written description issue "can arise in a number of different circumstances where it must be determined whether the subject matter of a claim is supported in an application as filed. See MPEP § 2163." However, MPEP § 2163.03 notes that "[w]hile a question as to whether a specification provides an adequate written description may arise in the context of an original claim which is not described sufficiently ..., there is a strong presumption than an adequate written description of the claimed invention is present in the specification as filed. ... Consequently, rejection of an original claim for lack of written description should be rare" (emphasis added). Further, MPEP § 2163.03 states that the written description requirement will "typically" arise in the following circumstances:

(1) amendment affecting a claim;

(2) reliance on filing date of parent application under 35 U.S.C. § 120;

(3) reliance on priority under 35 U.S.C. § 119; or

(4) support for a claim corresponding to a count in an interference.

Circumstance (1) does not apply at the present time, as claims 1-7, 19 and 26-27 are originally filed claims. Applicants respectfully submit that circumstances (2) and (3) are not applicable, as the provisional applications provide adequate written support for the presently claimed invention (please see the above comments). Meanwhile, circumstance (4) does not apply at the present time, as no interference is known at this time. As claims 1-7, 19 and 26-27 are originally filed claims, Applicants respectfully submit that a written description rejection is not appropriate. Further, Applicants note that the "examiner has the initial burden of presenting by a preponderance of the evidence why a person skilled in the art would not recognize in an applicant's disclosure a [written] description of the invention defined by the claims."

As to claim 4 in particular, Applicants agree with the Examiner that "applicants describe ... an NDV codon (AGA) replaced by codon (TCC) at position –2 of the F_0 cleavage site; NDV codon (AGG) replaced by codon (TCC) at position –5 of the F_0-cleavage site; ..." (Office Action, page 5, lines 11-15). As claim 4 discloses "(i) a codon, TCC, for serine in place of the codon for an arginine residue at the –2 position of the F_0 protein cleavage site of Newcastle disease virus wild type strain Beaudette C, and (ii) a codon, TCC, for serine in place of the codon for an arginine residue at the –5 position of the F_0 protein cleavage site ...", Applicants respectfully submit that the rejection of claim 4 under 35 U.S.C. § 112, first paragraph, was improper.

Further, Applicants submit that "Newcastle disease virus Z" is sufficiently described by the specification and originally filed claims (see claim 1).

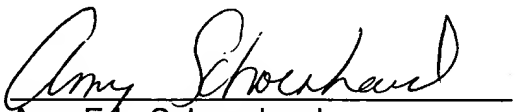
Accordingly, Applicants respectfully request reconsideration and withdrawal of the rejection of claims 1-7, 19 and 26-27 under 35 U.S.C. § 112, first paragraph.

In view of the remarks above, Applicants respectfully submit that this application is in condition for allowance and request favorable action thereon.

In the event this paper is not considered to be timely filed, Applicants hereby petition for an appropriate extension of time. The fee for this extension may be charged to our Deposit Account No. 01-2300, referring to Attorney Docket No. 108172-00070.

Please charge any fee deficiency or credit any overpayment to Deposit Account No. 01-2300, referencing Attorney Docket No. **108172-00070**.

Respectfully submitted,



Amy E.L. Schoenhard
Registration No. 46,512

Customer No. **004372**
ARENT FOX PLLC
1050 Connecticut Avenue, N.W., Suite 400
Washington, D.C. 20036-5339
Tel: (202) 857-6000
Fax: (202) 638-4810

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